RESPONSE TO RESTRICTION REQUIREMENT OF JUNE 26, 2006

REMARKS

Response to Restriction Requirement

The Office Action required Applicants elect of one of Groups I or II which are purportedly distinct inventions under 35 U.S.C. § 121. Applicants reserve the right to file divisional application(s) directed to non-elected subject matter.

Applicants hereby provisionally elect **Group II** (claims 17-27), drawn to, according to the Office Action, a method of preventing degradation of a hydrophobic group of ghrelin or its derivative in solution, elect **ghrelin**, elect **acetic acid** as a buffer agent, and **acetate buffer** as a buffer solution, **all with traverse.** Applicants respectfully request reconsideration of the restriction requirement.

According to PCT Rule 13.2, unity of invention exists between groups of inventions when there is a technical relationship among the claimed inventions involving one or more of the same corresponding special technical features. The Office Action asserts that the technical feature of Group I is a pharmaceutical composition comprising a ghrelin or its derivative. The Office Action asserts that WO 01/92292 teaches the special technical feature of claim 1. In contrast, the special technical feature of claim 1 is a pharmaceutical composition comprising ghrelin or its derivative in an aqueous solution with a pH between 2-7. WO 01/92292 does not teach the technical feature of claim 1 because it only discloses a pharmaceutically acceptable salt of truncated ghrelin analogs. Id. at 3 line claim 1. WO 01/92292 does not teach ghrelin or its derivative in an aqueous solution with a pH between 2-7. Since the special technical feature shared by Group I and II is novel there is no lack of unity. Rejoinder of Groups I and II and examination of claims 1-27 is respectfully requested.

Additionally, the Office Action did not elucidate reasons and examples as required by MPEP § 803 to support a species election between ghrelin and its derivatives. MPEP § 803.04. In In re Harnish, 631 F.2d 716, 206 U.S.P.Q. 300 (CCPA 1980), the court held that unity of invention exists where compounds included within a Markush group: (a) share a common utility and (b) share a substantial structural feature disclosed as being essential to that utility. In the instant case, ghrelin and its derivatives share the a common utility as they have the same function

and share substantial structure features. Therefore both share common structure and function and it is inappropriate to restrict between the two.

Furthermore, the Office Action did not elucidate reasons and examples as required by MPEP § 803 to support a species election between buffer agents and solutions. MPEP § 803.04. In In re Harnish, 631 F.2d 716, 206 U.S.P.Q. 300 (CCPA 1980), the court held that unity of invention exists where compounds included within a Markush group: (a) share a common utility and (b) share a substantial structural feature disclosed as being essential to that utility. In the instant case, all of the buffer agents and solutions share common utility and substantial structure features. Therefore all share structural features and function and it is inappropriate to restrict between the different buffer agents and solutions.

Applicants respectfully request that the Restriction Requirement be withdrawn and that all claims be prosecuted in the same patent application. At the least, Applicants respectfully request that ghrelin and its derivatives be examined together. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants reaffirm the election with **traverse** of **Group II** (claims 17-27), **ghrelin, acetic acid**, and **acetate buffer all with traverse**, holding claims 1-16 in abeyance under the provisions of 37 C.F.R. § 1.142(b) until final disposition of the elected claims.

CONCLUSION

Applicants maintain that the restriction requirement is improper and that all pending claims, *i.e.*, claims 1-27, should be examined for patentability. If the Examiner believes that prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

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